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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/044,643 | 01/11/2002 | William M. Grosse | 15966-748 CON (CURA-248 C | 8589 |

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| EXAMINER | |
|---|---|
| SPIEGLER, ALEXANDER H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/044,643 | GROSSE ET AL. | |
| | Examiner | Art Unit | |
| | Alexander H. Spiegler | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38 and 41, drawn to polypeptides, kits and compositions comprising said polypeptides, classified in class 530, subclass 350, for example.

II. Claims 5-14, 39 and 42, drawn to nucleic acids, kits and compositions comprising said nucleic acids, vectors and host cells, classified in class 536, subclass 23.1 and class 435, subclasses 320.1 and 325, for example.

III. Claims 15-17, 40 and 43, drawn to antibodies, kits and compositions comprising said antibodies, classified in class 530, subclass 387.1, for example.

IV. Claim 18, drawn to a method for determining the presence or amount of a polypeptide using an antibody, classified in class 435, subclass 7.1, for example.

V. Claims 19-21, drawn to drawn to a method for determining the presence or amount of a nucleic acid, classified in class 435, subclass 6, for example.

VI. Claims 22-23, drawn to methods of identifying an agent that binds to a polypeptide, classified in class 435, subclass 4, for example.

VII. Claims 24-25, drawn to a method for identifying an agent that modulates expression or activity of a polypeptide, classified in class 435, subclass 4, for example.

VIII. Claims 26-29 and 48, drawn to methods of treating or preventing a NOVX-associated disorder using a polypeptide, classified in class 514, subclass 2, for example.

IX. Claims 30-33, drawn to methods of treating or preventing a NOVX-associated disorder using a nucleic acid, classified in class 514, subclass 44, for example.

X. Claims 34-37 and 49, drawn to methods of treating or preventing a NOVX-associated disorder using an antibody, classified in class 514, subclass 1, for example.

XI. Claims 44-45, drawn to methods for determining the presence of or predisposition to disease associated with altered levels of a polypeptide, classified in class 435, subclass 4, for example.

XII. Claims 46-47, drawn to methods for determining the presence of or predisposition to disease associated with altered levels of a nucleic acid, classified in class 435, subclass 6, for example.

XIII. Claim 48, drawn to a method of treating a pathological state in a mammal, comprising administering to the mammal a polypeptide, classified in class 514, subclass 2, for example.

XIV. Claim 49, drawn to a method of treating a pathological state in a mammal, comprising administering to the mammal an antibody, classified in class 514, subclass 1, for example.

XV. Claims 50-52, drawn to methods of screening a candidate substance interacting an olefactory receptor polypeptide, classified in class 435, subclass 7.1, for example.

***Further Restriction***

2. The claims of Group I-XV are drawn to a multitude of nucleic acids, polypeptides, antibodies thereto and methods which use these compounds. Each of the different nucleic acids,

polypeptides, antibodies and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-XV, Applicant is additionally required to elect a **single** nucleic acid, polypeptide, or antibody (e.g., Applicants must elect one SEQ ID NO). For example, Applicants could elect Group II, and SEQ ID NO: 1 or Group XII and SEQ ID NO: 1. This requirement is not to be construed as a requirement for an election of species, since each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II and III, can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the

antibody of Group III can be used in immunoassay, the polypeptide of Group I can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II and III are patentably distinct from each other.

B) Inventions I and (IV, V, IX, X, XII and XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Group I are not required for the methods of Groups IV, V, IX, X, XII and XIV.

C) Inventions I and (VI-VIII, XI, XIII and XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I could be used in any of the methods of VI-VIII, XI, XIII and XV, or in an entirely different manner, such as in a purification reaction or in making antibodies.

D) Inventions II and (IV, VI-VIII, X-XI and XIII-XV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the nucleic acids of Group II are not required for the methods of Groups IV, VI-VIII, X-XI and XIII-XV.

E) Inventions II and (V, IX and XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group II could be used in any of the methods of V, IX and XII, or in an entirely different manner, such as in synthesizing proteins.

F) Inventions III and (V-IX, XI-XIII and XV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Group III are not required for the methods of Groups V-IX, XI-XIII and XV.

G) Inventions III and (IV, X and XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group III could be used in any of the methods of IV, X and XIV, or in an entirely different manner, such as in the production of anti-idiotypic antibodies.

H) Inventions IV-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to methods having different method steps, starting materials, and goals.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XV require different searches that are not co-

extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
January 26, 2004

CARLA J. MYERS
PRIMARY EXAMINER